

REMARKS

After entry of the amendments presented herein, claims 11, 14, 16-19, 22, 41, 43, and 45-50 are pending in the application. In view of the amendments and remarks set forth herein, Applicants respectfully request allowance of all pending claims.

35 U.S.C. 112 Rejections

Claims 11, 14, 16-19, 22, 41, and 43-50 stand rejected under 35 U.S.C. 112, second paragraph. Specifically, the Examiner asserts that the terms “agent to increase diffusion of the active substance through mucous in the nasal passage” and “permeation enhancer” are unclear. Applicants disagree, but have nevertheless amended claim 11 to read “agent to facilitate diffusion” as set forth in paragraph 57 of the application. Applicants submit that “permeation enhancer” is well defined in, for example, paragraph 52 of the present application. Applicants therefore respectfully request that this rejection be withdrawn. In addition, claim 14 has been amended to specify an agent to increase diffusion, and for this additional reason, Applicants request this rejection be withdrawn for claim 14.

The Examiner also asserts that the weight percent of the thickener, as a weight percent of the carrier, is not supported. Applicants have amended claim 11 and cancelled claim 44 to obviate this rejection.

Applicants submit that the only rejections to claims 14 and 46 are under this section and have been obviated. Accordingly, allowance of these claims is earnestly solicited.

35 U.S.C. 103 Rejections

Claims 11, 16-19, 22, 41, 42-45, and 47-50 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Re. 33, 465, issued to Eby in view of ES 2095183, HCAPLUS abstract 1994:638216, and DE 3431727. Applicants respectfully request reconsideration and withdrawal of this rejection.

Eby discloses a method to reduce a duration of common colds through use of zinc topically applied to the oral mucosa. Although the reference discloses that various forms of

applying the composition may be used (e.g., applying the composition to a nasal mucosa), Eby distinguishes himself from intranasal application of zinc compositions of the prior art that did not work. *See, e.g.,* Abstract. Although Eby *theorizes* as to why the prior-art compositions did not work, he does not provide any solution to the problem. Eby also does not disclose or suggest *any* composition, let alone *any enabled composition*, for application to a nasal membrane.

ES 2095183 discloses a drug delivery system that includes aqueous compositions. The aqueous compositions adhere to the nasal mucosa and include 8-12% poloxamer, less than 1% of bioadhesive polymer, and sodium chloride to obtain an isotonic final solution. The composition can be used with sympathomimetic agents, such as oxymetazoline.

DE 3431727 generally discloses a nose spray composition that includes zinc gluconate, which is applied using an atomizer. Nowhere does the reference teach or suggest any thickening agents or any motivation for adding thickening agents to the composition.

Claims 11, 16-19, 22, 41, 42-45, and 47-50 are nonobvious in view of the cited art, because no combination of the cited references teaches or suggest “an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt; and about 75 wt % to about 99.8 wt % carrier, the carrier comprising an agent to facilitate diffusion of the active substance through mucous in the nasal passage.”

The Examiner asserts that Eby does not provide a specific formulation for nasal administration and DE 3431727 provides motivation to nasally administer zinc gluconate for treating viral ailments. Applicants disagree with the Examiner's analysis for several reasons. First, Eby acknowledged that intranasal zinc formulations existed at the time of his invention. Eby distinguished his invention over the intranasal compositions—stating that such compositions did not work and that his invention is an improvement over zinc-based nasal sprays. *See* Abstract and Prior Art. Thus, Eby would not motivate someone to look at nasal delivery technology. Second, although Eby states that his method may include nasal application of a composition, he does not provide any examples of a nasal composition. Nor does he provide any explanation of why or how his nasal compositions vary from those of the prior art, which, according to Eby, don't work. Furthermore, Eby does not suggest how to overcome the shortcomings of the prior art. Eby *theorizes* that increasing zinc ion concentration from that

taught in the prior art, but he does not teach or suggest how to do this through nasal application of a composition.

DE 3431727 does not cure any of the deficiencies noted by Eby. Thus, there would be no motivation to combine the references. And, even if the references were combined, the combination does not teach or suggest the gel composition as set forth in the pending claims.

ES 2095183 discloses a gelling aqueous composition to deliver sympathomimetic agents, such as oxymetazoline. Eby explicitly distinguishes his invention from compositions that are used to merely treat symptoms (such as compositions that include oxymetazoline). For at least this reason, one would not be motivated to combine Eby with ES 2095183. Furthermore, even if one were motivated to look to nasal application technology in general, such would not necessarily lead to combining the teachings of Eby with the teaching of ES 2095185, since Eby acknowledges and references other prior art available at the time that relates to nasal application of zinc compositions, and further notes that the methods disclosed in those references were ineffective. In any event, no combination of Eby and ES 2095185 teaches or suggests “an active substance comprising about 0.185 wt % to about 2.8 wt % ionizable zinc salt; and about 75 wt % to about 99.8 wt % carrier, the carrier comprising an agent to facilitate diffusion of the active substance through mucous in the nasal passage.”

Furthermore, DE ‘727 acknowledges Eby’s zinc lozenges, discloses issues with such lozenges, and differentiates the invention from Eby’s lozenges. The reference further states that “[i]t is at the same time of great importance that the zinc gluconate solution be used in an atomizer...in order to achieve the most even distribution.” DE ‘727 does not disclose any compositions that include thickeners. Applicants submit that any composition including a thickener would not be obvious over this reference, since it would not be obvious to use a composition including a thickener with an atomizer.

Nevertheless, as noted above, even if the references were combined, the combination does not teach or suggest the claimed invention. Accordingly, Applicants submit the claims are patentable over the cited art.

Non-Statutory Double Patenting

Claims 11, 17-19, 22, 41, and 44-45 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-6 of United States Patent No. 6,673,835 in view of ES 2095185 and DE 3431727. Applicants herewith submit a terminal disclaimer to obviate this rejection.

Claims 49-50 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 11/781,396; claims 1-20 of copending Application No. 11/748,668; claims 1-18 of copending Application No. 11/748,653; claims 1-20 of copending Application No. 11/749,111. Applicants herewith submit a terminal disclaimer to obviate this rejection.

CONCLUSION

In view of the foregoing remarks, Applicants believe that the pending claims are allowable over the cited art and Applicants therefore earnestly request allowance of all pending claims. The undersigned requests a telephone call at the telephone number listed below if, for any reason, the Examiner deems one or more of the pending claims unpatentable.

Applicants authorize and respectfully request that any extension of time fees due be charged to Deposit Account No. 19-2814. **This statement does NOT authorize charge of the issue fee.**

Respectfully submitted,

Date: April 16, 2009

By:



Cynthia L. Pillote
Reg. No. 42,999

SNELL & WILMER L.L.P.

One Arizona Center
400 East Van Buren
Phoenix, AZ 85004-2202
Phone: (602) 382-6296
Fax: (602) 382-6070
cpillote@swlaw.com